K022210

OCT 0 4 2002

SECTION 16: 510K SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

16.1: ADMINSTRATIVE INFORMATION

Name and Address

Submitted by: Cardiac Science Incorporated
16931 Millikan Ave
Irvine, CA 92606

Contact Person: John Carline
Telephone No.: 952-939-4181, x2978
Facsimile No.: 952-939-4191
Email: jcarline@cardiacscience.com

Date Prepared: July 1, 2002

16.2: DEVICE INFORMATION

Common or Usual Name: Disposable Polymer (Hydrogel) External Monitoring, Pacing, Cardioversion and Defibrillation Electrode

Trade Name: Powerheart® Multifunctional Electrodes Models 9640 and 9650

16.3: DEVICE CLASSIFICATION

Classification Name: Multifunctional Electrocardiograph Electrode
21 CFR 870.2360 MLN
Device Class: III

16.4: DEVICE DESCRIPTION

The Multifunctional Electrodes consist of a pair of single-use, hydrogel polymeric self-adhesive electrode pads of equal dimension intended to be used for defibrillation, synchronized cardioversion, ECG monitoring and external pacing. The Multifunctional Electrodes are for use with the Powerheart® Cardiac Rhythm Module and the Powerheart® Automatic External Cardiac Defibrillator (AECD). The electrodes are packaged in a pouch to prevent the gel from drying out.

The Model 9640 contains an additional small right leg drive (RLD) electrode on the sternum pad. The RLD electrode is used to eliminate the voltage potential between the patient and defibrillator's ground reference.

Inside each electrode connector is an electrode ID chip. The ID chip allows the defibrillator to read the electrode specific information contained in the ID chip.

16.5: INDICATION FOR USE

The Multifunctional Electrodes, Models 9640 and 9650 are single use and intended to be used for defibrillation, synchronized cardioversion, ECG monitoring, and external pacing.

16.6: IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Contour Medical Technology (Ludlow Co.)	Disposable Hydrogel Defibrillation Electrode Model MFE-116	K960329	July 1, 2002

16.7: SUBSTANTIAL EQUIVALENCE

The Multifunctional Electrodes, Models 9640 and 9650 covered by this submission are substantially equivalent to other legally marketed electrodes for semi-automatic low power DC defibrillators. Specifically, the Multifunctional Electrodes are substantially equivalent to Contour Medical Technology (Ludlow Company) Disposable Hydrogel Defibrillation Electrode, Model MFE 116 cleared under premarket 510(k) notification, K960329 on July 2, 1996.

16.8: PERFORMANCE DATA

Performance testing was conducted to verify that the Multifunctional Electrodes meet the applicable requirements for single use hydrogel electrodes in accordance with industry standards ANSI/AAMI DF-2, ANSI AAMI DF-39, and. ANSI/AAMI EC-12. In addition, biocompatibility assessments were conducted on the components that come into contact with the patient's skin. The Multifunctional Electrodes, Models 9640 and 9650 were found to perform as intended.

16.9: CONCLUSIONS

Cardiac Science has demonstrated through its evaluation and testing of the Multifunctional electrodes, Models 9640 and 9650 that the device is equivalent to the predicate device with respect to intended use, technological characteristics, materials, function and safety and effectiveness.

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 4 2002

Cardiac Science, Inc.
c/o Mr. John Carline
Manager, Regulatory Affairs
16931 Millikan Avenue
Irvine, CA 92606

Re: K022210
Trade Name: Multifunctional Electrodes, Models 9640 and 9650
Regulation Number: 21 CFR 870.1025
Regulation Name: Automated External Defibrillator Electrode
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: July 1, 2002
Received: July 8, 2002

Dear Mr. Carline:

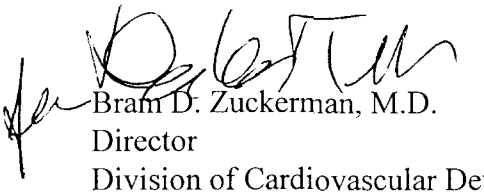
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Multifunctional Electrodes
Models 9640 and 9650

Indications for Use: The Multifunctional Electrodes are single use and intended to be used for defibrillation, synchronized cardioversion, ECG monitoring and external pacing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022210

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)